No. 24-1285

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.

Intervenors.

Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

MASIMO CORPORATION AND CERCACOR LABORATORIES, INC.'S NONCONFIDENTIAL OPPOSITION TO APPLE INC.'S EMERGENCY MOTION TO STAY ENFORCEMENT OF ITC'S ORDERS PENDING REVIEW

Jonathan E. Bachand
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue N.W.
Suite 900
Washington, DC 20006
(202) 640-6400

Joseph R. Re
Principal counsel
Stephen C. Jensen
Sheila N. Swaroop
Brian C. Claassen
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

Counsel for Intervenors Masimo Corporation and Cercacor Laboratories, Inc.

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Rule 25.1(e)(1)(B) Statement: The material omitted on pages 7 and 9 are images of Masimo's confidential product development for the Masimo W1 Watch. Masimo designated this information as Confidential Business Information under the Administrative Protective Order in effect in ITC Investigation No. 1276. The material omitted on pages 1-2 and 19 contain information that Appellant Apple Inc. designated as confidential regarding its proposed redesign for the infringing Apple Watches.

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OTHER AUTHORITIES

Intervenors Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo") oppose Appellant Apple Inc.'s motion for a stay pending appeal. ECF 7-8 ("Stay-Mot."). The Commission already concluded that Apple failed to show any of the *Standard Havens* factors support a stay. Stay-Add-1-15[1]; *see also* Stay-Add-138-141 (denying request to delay enforcement). Apple's motion here similarly fails.

Apple presented to the Commission no evidence of harm, much less irreparable harm. The Commission found "Apple's alleged irreparable injuries are pure attorney argument supported by no evidence." Stay-Add-11. Apple presents similar attorney arguments here. In contrast, Masimo submits a detailed declaration from its founder and CEO, Joe Kiani, explaining Masimo's extensive injury from a stay.

Apple's irreparable-harm arguments lack any nexus to the claimed inventions. Indeed, Apple's requested relief shows Apple does not need to sell watches that measure blood oxygen. Apple argues it would be able to sell its "flagship Watch products" if either (1) this Court stays the remedial orders against watches with the Blood Oxygen feature, ***or*** (2) U.S. Customs and Border Protection ("CBP") approves a watch version that Apple represents "Apple Confidential Business Info

[1] "Stay-Add" refers to the Addendum to Apple's stay motion. "MAS-ADD" refers to Masimo's Addendum to its Opposition.

Apple CBI,"[2] Stay-Mot. 1-2. Thus, Apple seeks to sell as many "flagship" watches as possible—***with or without*** the infringing feature. Apple's purported harm has no nexus to the claimed invention.

Apple's claim is also facially implausible because, as the Commission found, the remedial orders "affect just a portion of one product line in Apple's large suite of product and service offerings." Stay-Add-12. Apple is the world's largest company, with a market cap approaching $3 trillion. And Apple ignores that any harm to its "goodwill and reputation" arises from the findings that Apple infringed Masimo's patents—findings Apple does ***not*** dispute on this motion. Stay-Mot. 3.

Apple also ignores that its Apple Watch SE is "not affected by the Commission's remedy." Stay-Add-12 n.3. That watch has nearly the same features as infringing watches except the infringing blood-oxygen sensor. Apple also ignores that it may provide the infringing watches to its existing users under the remedial orders' repair-and-warranty exemptions. Stay-Add-19-20, 26-27.

Moreover, Apple cannot show a strong likelihood of success on any of the "three reasons" identified in its Motion. Stay-Mot. 3. First, the Commission supported its domestic-industry analysis with substantial evidence. Second, the Commission committed no legal error in rejecting Apple's obviousness defense and

[2] Emphasis added unless noted otherwise.

substantial evidence supported its underlying findings. Third, Apple cannot show the Commission abused its discretion in holding that Apple waived its prosecution laches defense. Regardless, Apple cannot show the Commission's findings rejecting that defense on the merits lack substantial evidence.

Apple's public-interest arguments are also unsupported. As with its irreparable-harm arguments, Apple never ties its arguments to the infringing feature. And Apple again ignores the Apple Watch SE and the remedial orders' repair-and-warranty exemptions. Stay-Add-14, 19-20, 26-27. Apple also ignores abundant evidence exposing that Apple's pulse oximetry performs poorly and that the public would be better off without it. Substantial evidence supports the Commission's conclusion that "the public interest does not support a stay pending appeal, and in fact ***counsels against*** granting a stay." Stay-Add-14.[3]

I. BACKGROUND

A. Masimo Becomes An Industry Leader

Masimo, based in Irvine, California, is an American success story. Kiani ¶¶ 3-14. Masimo was a "garage startup" founded by Kiani with the goal of solving a pulse-oximetry problem that the industry thought was unsolvable. *Id.* ¶¶ 5-6. After

[3] Alleged confidentiality does not justify Apple's failure to address the Commission's opinion. Stay-Mot. 1 n.1. Moreover, Masimo informed Apple five days before Apple filed its motion that nothing in the opinion was confidential. MAS-ADD-453. And Apple designated nothing confidential. *Id*.

succeeding, Masimo now manufactures and sells pulse oximeters that professional caregivers use to monitor over 200 million patients a year. *Id.* ¶ 4. Masimo's pulse oximetry is the standard in nine of the top ten hospitals in the United States. *Id.*

For the past decade, Masimo has been offering pulse oximeters with reliable, medical-grade measurements directly to consumers. *Id.* ¶¶ 12-14. Masimo recently received FDA clearance for the Masimo W1 health-tracking watch, which includes Masimo's continuous hospital-grade pulse oximetry. MAS-ADD-404-419; Kiani ¶¶ 19-20. That clearance authorizes over-the-counter sales for medical purposes. Kiani ¶ 20.

B. Masimo Encounters Apple

In May 2013, Apple pursued a meeting with Masimo about integrating Masimo's technology in Apple's products. Kiani ¶ 24; MAS-ADD-039 at 104:11-22; MAS-ADD-158-159. Instead of partnering with Masimo, Apple hired Masimo employees, including Masimo's Chief Medical Officer and the Chief Technical Officer of a Masimo spin-off, Cercacor. Kiani ¶ 25. Apple ultimately hired over twenty Masimo and Cercacor employees. *Id.* In 2015, Apple introduced the first Apple Watch, which did not contain pulse oximetry. *Id.* ¶ 26. That confirmed Kiani's understanding of the repeated, but false, representations from Masimo's former Chief Medical Officer that Apple had no interest in pulse oximetry. *Id.*

As the Final ID found, "Apple did not implement a blood oxygen feature in any of the first six Apple Watches that were commercially released from 2015-2019." Stay-Add-309. Apple's engineers testified that they found measuring oxygen saturation at the wrist very difficult. Stay-Add-309-311 (citing evidence recognizing "invention is required").

In September 2020, Apple released the Series 6 Watch with a "blood-oxygen sensor" to capitalize on the "chaos of COVID-19," though Apple knew its sensor was not ready. MAS-ADD-426-428; MAS-ADD-546-547. At the same time, Apple introduced its Watch SE, a lower-cost watch without a blood-oxygen sensor. MAS-ADD-548, video at 21:30-21:36.

Masimo believed Apple's Series 6 Watch infringed Masimo patents and, because of the Watch's poor performance, concluded Apple would destroy consumer confidence and demand for reliable, medical-grade pulse oximetry. Kiani ¶¶ 31-33. Therefore, Masimo brought this ITC action seeking prompt exclusion of the Series 6. *Id.* ¶ 34-35.

II. ARGUMENT

A. The Agreed-Upon Law Governing Stays Pending Appeal

The parties agree on the four factors governing Apple's motion. Stay-Mot. 5-6 (likelihood of success, irreparable injury to applicant, injury to other parties, and

public interest); *see also Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990).

The Commission found that Apple failed to show that any of the four factors support a stay. Stay-Add-6-14. Before this Court, Apple had the opportunity to supplement the record but added nothing. *See* Fed. Cir. R. 27(a)(4).

B. Apple Is Not Likely To Succeed On This Appeal

1. Apple Is Unlikely To Succeed On Its Domestic-Industry Challenge

Apple argues the Commission's domestic-industry analysis erred because "no patent-practicing article existed at the time of the complaint." Stay-Mot. 6. Apple challenged Masimo's domestic industry three times and failed each time. *See, e.g.*, MAS-ADD-022-035 (Order No. 31 denying Apple Motion for Sanctions); Stay-Add at 215-247 (Final ID); Stay-Add at 96-98 (Commission Opinion). In rehashing its failed arguments, Apple ignores the evidentiary record, the detailed findings in the Final ID, and the Commission's adoption of those findings.

Apple incorrectly argues Masimo was "unable to provide evidence of a single pre-Complaint item that matched the CAD drawing or practiced the claims." Stay-Mot. 10. Masimo described the CAD drawings attached to the Complaint as "representative" of Masimo's domestic industry products. Stay-Add-505 (Complaint ¶ 89) (attaching MAS-ADD-003-020). A Masimo engineer testified the CAD drawings "accurately represent[] the sensing features" and any small

differences do not relate to the pulse oximetry sensor. MAS-ADD-078-079 at 477:9-478:8. The only "differences" relate to unclaimed aspects.[4] MAS-ADD-175-176 at 91:18- 92: 24 (physicals have no "metal electrodes" (for ECG) or "wireless-charging coil"). Apple never argued that theses minor differences were recited in the asserted patent claims. And as shown below, the pre-Complaint RevE watches were very similar to the Complaint's CAD drawings.

CPX-019C	CPX-065C	Complaint's CAD Drawing
Confidential Masimo Watch Project Development		ECG electrodes

MAS-ADD-395-396 (annotated). Regardless, CAD drawings are not patent-practicing articles. Rather, the patent-practicing articles included Masimo's RevA, RevD, and RevE watches.

Masimo provided detailed evidence regarding the Masimo Watch project, including multiple physical samples of patent-practicing articles. *See, e.g.*, MAS-ADD-181-225 (summarizing Masimo Watch project). In April 2022, the ALJ found that "[w]ith respect to the 'Masimo Watch' samples that were referenced in

[4] The claims at issue are Claims 22 and 28 of U.S. Patent No. 10,912,502 (Stay-Add-774-775) and Claims 12, 24, and 30 of U.S. Patent No. 10,945,648 (Stay-Add-884-885).

the Amended Complaint, there is no dispute that multiple 'Masimo Watch' ***physical items existed*** at the time of the Amended Complaint." *See* MAS-ADD-032. And before this Court, Apple does not dispute that the Masimo RevA watch was completed before the Complaint. Nor does Apple dispute that the RevA, RevD, or RevE watches practice the asserted patents. Stay-Mot. 8.

At the evidentiary hearing, Masimo's witnesses confirmed that, before Masimo's July 2021 Complaint, Masimo at least:

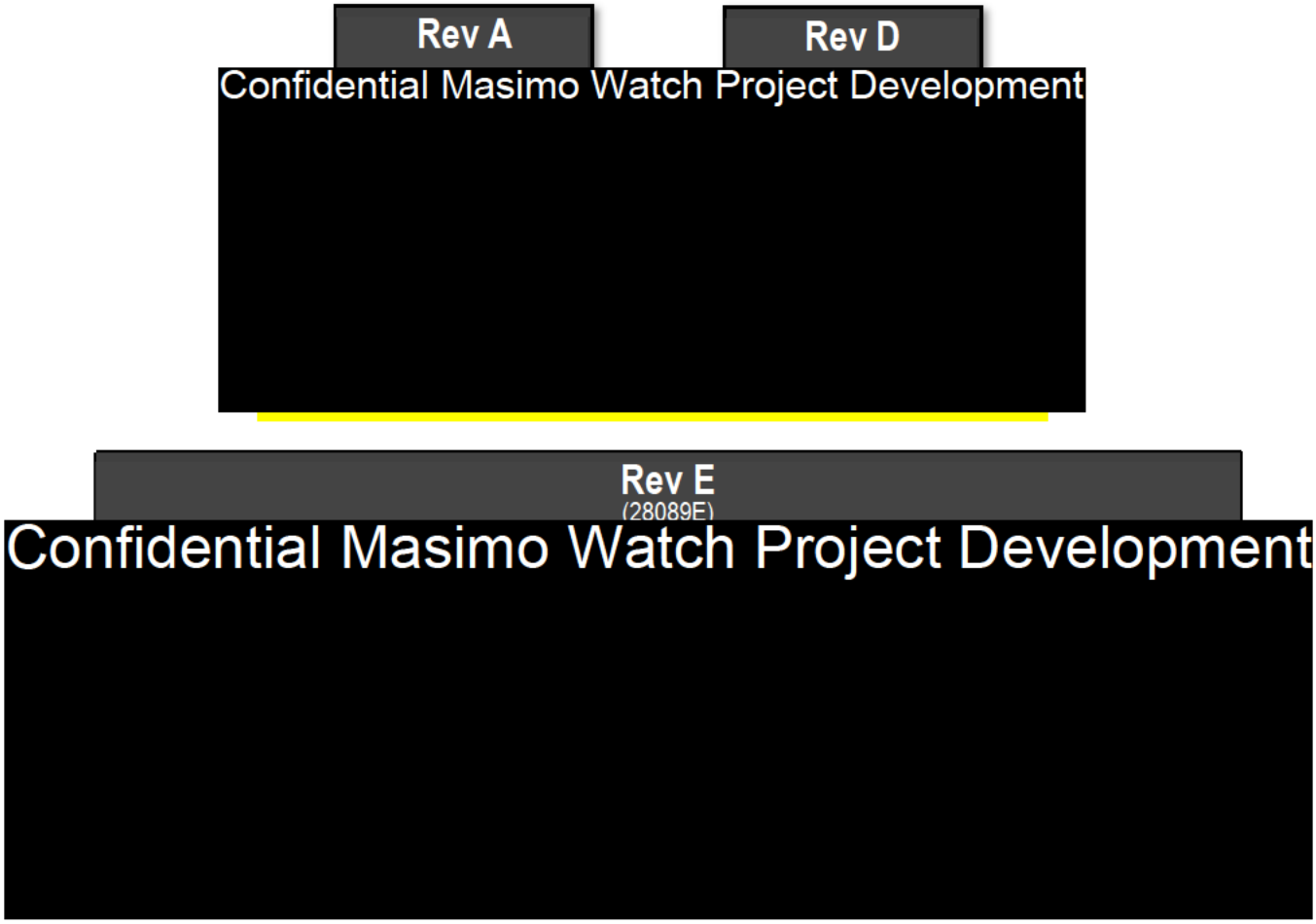
(1) manufactured multiple patent practicing articles starting in "late 2019," and conducted clinical testing on the RevA watches in 2020, MAS-ADD-046 at 250:6-14; MAS-ADD-109-116 (RevA clinical testing);

(2) manufactured RevD watches around early 2021, MAS-ADD-057-058 at 276:12-277:12; MAS-ADD-118-130; MAS-ADD-178 at 239:19-240:13;

(3) manufactured RevE watches around March 2021, which were fully operational by May 2021, Stay-Add-244; MAS-ADD-074-076 at 398:20-23 and 458:1-459:3; and

(4) conducted clinical studies on those RevE watches that started no later than June 2021 (MAS-ADD-063-067 at 313:14-317:20).

Masimo also submitted physical examples of these patent-practicing articles, as shown below:



MAS-ADD-162 (RevA); MAS-ADD-165 (RevD); MAS-ADD-168 (RevE); MAS-ADD-170 (RevE); MAS-ADD-172 (RevE).

The Final ID found Masimo's "RevA, RevD, and RevE devices have been shown to be articles protected by the claims of the [Masimo] patents ***existing at the time of the complaint***." Stay-Add-243; *see also* Stay-Add-219 ("There is no dispute that the RevA and RevD sensors were made before the filing of the Complaint."); Stay-Add-244 ("The evidence shows that at least one of the RevE devices produced [MAS-ADD-167-168] existed at the time of the complaint"). These findings were

part of a detailed thirty-page analysis of Masimo's pre-Complaint articles. *See* Stay-Add-215-245.

The Final ID also credited Masimo testimony "identif[ying] testing of blood oxygen functionality conducted in 2020 using prototype designs consistent with the RevA sensor, additional testing in the timeframe of the RevD devices in early 2021, and further testing of RevE devices in June 2021." Stay-Add-221 (citing MAS-ADD-047-059 at 260:11-268:21, MAS 270:17-22, 276:12-278:3; MAS-ADD-065-066 at 315:16-316:18; MAS-ADD-104-141). The Commission adopted these findings. Stay-Add-45.

Instead of addressing these findings, Apple ignores them and incorrectly asserts the Final ID relied only upon circumstantial evidence. Apple falsely asserts "there was no direct evidence" of patent-practicing articles at the time of the Complaint. Stay-Mot. 9. Apple relies on post-Complaint software updates on RevD and RevE watches for this argument, but ignores (1) the testimony from Masimo's witness that all versions of Masimo's software could determine oxygen saturation and pulse rate, MAS-ADD-070 at 346:6-16; MAS-ADD-077 at 476:1-4, and (2) the clinical studies on each of RevA (MAS-ADD-109-116) and RevE (MAS-ADD-132-141) proving the watches measured oxygen saturation before the Complaint. MAS-ADD-046 at 250:6-14; MAS-ADD-057-058 at 276:12-277:12; MAS-ADD-063-067 at 313:14-317:20.

Regardless, relying on circumstantial evidence is appropriate and sufficient. *See Moleculon Research Corp. v. CBS, Inc*., 793 F.2d 1261, 1272 (Fed. Cir. 1986) ("'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'") (*quoting Michalic v. Cleveland Tankers, Inc*., 364 U.S. 325, 330 (1960)); *Certain Filament Light-Emitting Diodes and Prods. Containing Same*, 337-TA-1220, Comm'n Op., 2022 WL 766226, *18 (Mar. 8, 2022) (circumstantial evidence supporting domestic-industry technical prong).

Because Apple ignores and contradicts the record, it cannot succeed in showing the Commission's domestic-industry findings lack substantial evidence.

2. Apple Is Unlikely To Succeed On Its Obviousness Defenses

Apple argues the "Commission erred by rubber-stamping Masimo's attempt to stretch clinical-focused patents to cover consumer products." Stay-Mot. 11 (Section B heading). The Commission did not "rubber stamp" anything. The Commission's work was extensive, as shown by its detailed 337-page Final ID, 124-page opinion on review, and 14-page opinion denying Apple's Stay Motion. Stay-Add-1-497. Moreover, Apple's argument that the Commission "stretched" Masimo's patents is nonsensical because Apple does not challenge claim construction or infringement. Nor does Apple contest the Commission's rejection of its written-description defense.

Rather, Apple contests the Commission's rejection of Apple's obviousness defense based on Lumidigm prior art. In so doing, Apple never acknowledges it had the burden to prove supporting facts by clear and convincing evidence.

a. The Commission Never Held Lumidigm Must Be "More Enabling" Than The Masimo Patents

Apple contests the Commission's adoption of the Final ID's rejection of Apple's Lumidigm-based obviousness defense. Stay-Mot. 12. Apple contends that ruling "rested in large part on the legal error that prior art references must render obvious more than the challenged claims enable—or, indeed, more than the challenged claims require." *Id*. Apple claims the Commission required it "to show the prior art enables more than the patents-at-issue." *Id.*

The Commission did no such thing. At best, Apple misinterprets the Final ID and inaccurately attributes a position to the Commission that the Commission expressly rejected. In denying Apple's Stay Motion, the Commission explained:

> ***Apple misconstrues the Final ID***, and Apple's argument (also presented in its petition for review of the Final ID) was already considered and rejected by the Commission. ***Neither the Final ID nor the Commission required Lumidigm to enable more than the asserted patent claims***. Rather, the Commission properly analyzed Lumidigm and other evidence to determine if a person of ordinary skill in the art would have been motivated to modify Lumidigm's wristwatch to measure oxygen saturation to arrive at the alleged invalidating device with a reasonable expectation of success.

Stay-Add-10 (citations omitted).

Apple complains about the Final ID's finding that Lumidigm does not enable taking "oxygen saturation" at the wrist, even though none of the asserted claims recite measuring on the wrist. Stay-Mot. 13. As the Commission explained in denying the Stay Motion, Apple created the issue:

> While measuring oxygen saturation at the wrist is not claimed, Apple chose to base its invalidity theory on measuring blood oxygen saturation at the wrist being taught or suggested by Lumidigm to a person of ordinary skill in the art at the time of the invention.
>
> Here, the Commission properly found that Lumidigm, alone or combined with knowledge in the art at the time of the invention, did not enable measuring oxygen saturation at the wrist, and therefore a person of ordinary skill in the art would not have reasonably expected success at arriving at the device serving as the basis of Apple's obviousness theory.

Stay-Add-10. (citations omitted).

The above passages show Apple contrived the alleged legal errors. Apple disputes the ***factual*** findings on Lumidigm—not any legal issue. What Lumidigm teaches presents a pure question of fact. *See Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). Because abundant evidence supports the Commission's findings, Apple cannot succeed on appeal.

b. <u>Apple's New Invalidity Arguments Are Without Merit</u>

Apple never presented its remaining invalidity arguments to the Commission on its previous stay motion. Apple now challenges the Commission's findings that Lumidigm does not teach or suggest separate "transmissive windows" or "optically transparent material" extending across openings. Stay-Mot. 14.

First, the Final ID did not hold "the Lumidigm reference satisfies the limitations in question" as Apple represents. *Id.* The Final ID found "the evidence ***does not*** clearly and convincingly show a reason to incorporate [optically-transparent material] 'within' each opening." Stay-Add-283. Second, the Commission did not reverse this finding, as Apple represents. Rather, it "***affirm[ed] and adopt[ed]*** the Final ID's findings and conclusion that neither Lumidigm nor a combination of Lumidigm and other prior art teaches or suggests an 'optically-transparent material ***within*** each of the openings.'" Stay-Add-65 (citing Stay-Add-281-284). Apple cannot show either finding lacks substantial evidence.

Apple next argues as if the Commission had to adopt Apple's expert testimony about Lumidigm referencing "fiber optic faceplates." But that testimony does not track the claim limitations and merely states what "could be implemented," not what would have been obvious to implement. The Commission correctly criticized such testimony. Stay-Add-66; *see, e.g., Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) ("The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether 'they ***would have been motivated to do so***.'"); *see also Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1158 (Fed. Cir. 2022).

Moreover, the Commission explained why its rejection of Apple's obviousness theories based on Lumidigm was consistent with the USPTO's rejection

of Apple's reliance on Lumidigm ***in four separate IPRs***. Stay-Add-67-69; MAS-ADD-234-343.[5] The USPTO rejected Apple's "proposed amalgamation of prior art teachings" as a "convoluted combination" that was "grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art." MAS-ADD-334-335.

Citing its expert's testimony, Apple alleges a person of ordinary skill would have reason to modify Lumidigm to use "fiber optic faceplates, which ***could*** be implemented as either (1) a single faceplate or (2) as individual faceplates over each opening." Stay-Mot. 14–15 (citing, *e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)). *KSR* and its progeny do not apply because no testimony supports Apple's assumption that its obviousness theory is based on a "small number of alternatives." Stay-Mot. 14-15. Further, Apple waived this argument by never raising it before.

Apple challenges the Final ID's finding and the Commission's affirmance upholding Claim 22. Stay-Mot. 15. Apple argues that Lumidigm renders the claim obvious based on expert testimony that does not even mention Lumidigm. *Id.* (citing Stay-Add-529-530). But the Commission has no obligation to address irrelevant

[5] Apple requested the Commission take judicial notice of those IPRs before knowing the outcomes, reflecting Apple's prior position to the Commission that the USPTO is the "lead agency in assessing patentability, or validity, of proposed or issued claims." MAS-ADD-430-432.

testimony. Because the Commission's Lumidigm's findings are supported by substantial evidence, Apple is not likely to succeed on its obviousness defense.

3. Apple Is Unlikely To Succeed On Its Waived Defense Of Prosecution Laches

The Commission rejected Apple's prosecution-laches argument as waived and lacking evidence. The Commission found "Apple ***waived*** its opportunity to challenge this issue by not properly presenting it in its petition for review of the Final ID." Stay-Add-8. As the Commission explained, Apple's Petition for Review violated Commission rules by merely incorporating by reference Apple's unsuccessful prosecution laches arguments before the ALJ. *Id.* (relying on 19 C.F.R. § 210.43(b)(2)). Apple cannot show the Commission abused its discretion applying its own rules.

Regardless, the Final ID rejected Apple's prosecution-laches defense on the merits. Stay-Add-330-333, 405. The Final ID found no prosecution delays, relying on unrebutted testimony from the former Commissioner of Patents, Robert Stoll, and Masimo's prosecuting attorney. *Id*. at 331-332. Apple notes that the Final ID's finding that Masimo maintained a "continuous unbroken chain" of applications, by itself, would not answer whether laches applies. Stay-Mot. 17 n.7. The finding of no delay renders Apple's note irrelevant.

The Final ID also rejected the argument Apple repeats here that Masimo purportedly delayed writing patents to cover Apple's Watches after they were

released. Stay-Add-333. The Final ID found (1) "Apple has ***not*** provided evidence showing that newly asserted claim limitations were specifically drawn to the Accused Products" and (2) even if there were such evidence, nothing is improper about drafting claims to cover competitors' products. Stay-Add-334 n.65. The ID also cited Masimo's argument that "there can be no prejudice to Apple because the specification of the [Masimo] patents was published in February 2010." Stay-Add-332.

The Final ID also rejected Apple's argument repeated here that Masimo should have filed certain patent applications earlier. Stay-Mot. 16; Stay-Add-333. The Final ID found that "Apple failed to identify actions by Masimo that resemble the type of conduct recognized by the Federal Circuit as unjustifiable prosecution delay." Stay-Add-333-334.

Because of Apple's waiver, the Commission's Final Determination unsurprisingly makes no mention of Apple's laches defense and thus affirmed and adopted the Final ID's analysis rejecting this defense. Stay-Add-45. Apple cannot show it is likely to succeed on its prosecution-laches defense.

C. Apple Has Not Shown Any Irreparable Harm

The Commission found Apple offered no evidence of irreparable harm, especially because the remedial orders "affect just a portion of one product line in

Apple's large suite of product and service offerings." Stay-Add-12. Here, Apple rehashes the same arguments the Commission rejected and offers no new evidence.

For example, Apple ***argues*** it "is losing goodwill and suffering reputational damage from being unable to provide U.S. consumers with its flagship Apple Watch products." Stay-Mot. 18 (citing *Celsis In Vitro*). The Commission rejected this assertion as "pure attorney argument supported by no evidence." Stay-Add-11.

Apple also repeats its assertions of harm based on purported "supply-chain constraints." Stay-Mot. 19 (citing Davis Decl. ¶ 19 at Stay-Add-595-596). The Commission also found that argument unpersuasive. Stay-Add-140. Moreover, Apple and its declarant ignore that Apple sells its Watch SE with virtually all the features of the excluded watches but without the infringing blood-oxygen sensor.

Apple also had two-and-a-half years to prepare for possible exclusion, including an entire year after the Final ID. Apple cannot complain about the consequences of its own failure to prepare for exclusion.

In a footnote, Apple argues it will suffer "substantial and unpredictable deleterious consequences." Stay-Mot. 19 n.9. It cites two paragraphs, one from each of two declarations, to argue "that it would be 'highly disruptive' for Apple Watch users to 'switch to another device.'" *Id*. (citing Stay-Add-588 and Stay-Add-610-611). But the remedial orders do not impact any existing users. The remedial orders also have repair-and-warranty exemptions so current users have no need to switch

to another watch. Moreover, the Apple Watch SE has ***all*** the health features the declarants mention.

Finally, Apple argues it needs time for the CBP's Exclusion Order Enforcement Branch to rule that "Apple's redesigned Watches fall outside the Commission's Orders because they Apple Confidential Business Info the Commission found to be infringing."[6] Stay-Mot. 20. By this argument, Apple admits it will suffer no irreparable harm if the CBP rules as Apple predicts. Indeed, Apple never argues that the blood-oxygen feature has any value at all to Apple, much less that it is critical. That failure to connect any harm to the infringing feature is fatal. *See, e.g., Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (irreparable harm requires a "sufficiently strong causal nexus" between "alleged harm to the alleged infringement.").

D. <u>A Stay Through Appeal Would Harm Masimo</u>

Masimo filed its Complaint in July 2021. After two-and-a-half years, a thorough Commission investigation, and four PTO denials of Apple IPR petitions

[6] Masimo maintains that Apple did not "Apple Confidential Business Info [redacted]" in its "redesign" before CBP. Masimo cannot explain why because Apple required Masimo not use any part of the CBP proceeding in any other proceeding. Apple's position before the CBP reflects its "high risk" legal strategy to "steer the ship as close to that line [dividing legally risky actions from clearly safe actions] as you can, because that is where the competitive advantage lies." MAS-ADD-422. If the CBP agrees with Masimo and rejects Apple's "redesign," Apple has only itself to blame because it had ample opportunity to actually "Apple Confidential Business Info [redacted]."

challenging the Masimo patents supporting the remedial orders, Apple requests additional time to infringe. As explained in the Kiani Declaration, granting Apple's request would harm Masimo in many ways.

Masimo's goal has always been to get medical-grade pulse oximetry to as many people as possible. Kiani ¶ 5. Over the last ten years, Masimo has invested heavily on applying its pulse oximetry technology to wrist-worn devices for consumers. *Id.* ¶¶ 15-23. Because Masimo has always been focused on the importance of accurate and reliable blood-oxygen measurements, the public's positive perception of that parameter is vital to Masimo's success. *Id.* ¶¶ 50-51.

Unfortunately, most consumers are now likely to be exposed to pulse oximetry for the first time using the Apple Watch. *Id.* ¶ 50. But the Apple Watch performs pulse oximetry poorly. *Id.* ¶¶ 43-46, 48-49; MAS-ADD-377-392 (Masimo Whitepaper). When consumers assume that Apple products are the best available, they will lose confidence in the blood-oxygen parameter. Kiani ¶ 50. That in turn destroys demand for Masimo's reliable, medical-grade pulse oximetry. *Id.* ¶¶ 50-54. Moreover, because of Apple's pricing among its watches, consumers will incorrectly believe that reliable pulse oximetry is worth only about $120-$150. *Id.* ¶ 53.

A stay would also frustrate Masimo's incentive to innovate, contrary to the goal of the patent system. *Id.* ¶¶ 61-69. Masimo, like other innovative companies,

greatly depends on the patent system. *Id.* ¶¶ 61-65, 75. Masimo disclosed to the public how Masimo's technology works in exchange for a limited exclusionary right. Masimo invested many resources in developing wearable medical-grade pulse oximetry while Apple, almost overnight, dominated the consumer field with an infringing inferior version of Masimo's technology.

A stay would demoralize Masimo's scientists and engineers as they see a large company like Apple continuing to infringe. *Id.* ¶¶ 66-69. This is exacerbated because Apple hired their colleagues to assist in developing the Apple Watch, lost before the Commission, and lost before the Patent Office in challenging Masimo's patents. *Id.* ¶¶ 68-69. Failing to recognize and reward these scientists and engineers for inventing innovative new products would reduce their incentive to create and invent more innovative solutions to medical problems.

Allowing Apple to continue selling infringing products also harms Masimo by forcing Masimo to compete against its own patented technology. *Id.* ¶ 61. Apple appears to agree, at least when Apple asserted its own patents against Masimo. MAS-ADD-443 (arguing that allegedly infringing product causes irreparable harm by "forcing Apple to compete against its own patented invention"); MAS-ADD-444 (arguing that allowing a competitor to establish a "foothold" through infringing products causes irreparable harm).

A stay would also greatly hurt Masimo's reputation. Kiani ¶¶ 55-60. News of the remedial orders has been prolific and widespread. *Id.* ¶ 55. Apple has taken advantage of the Court's interim stay and would take advantage of a longer stay to continue its publicity campaign that Masimo's infringement claims lack merit and that Masimo somehow copied Apple's technology. *Id.* ¶¶ 58-60.

As the Commission found in denying Apple's Stay Motion, Masimo "would suffer some harm by granting the stay." Stay-Add-12. It also correctly found Masimo "will be irreparably injured by a stay that denies its patents the full term to which they are entitled." *Id*. That harm is particularly significant because the Masimo patents are nearing their expiration in 2028. Kiani ¶¶ 36, 71. And the Kiani declaration reinforces the Commission's findings that Masimo would suffer harm from a stay. By contrast, as the Commission found, Apple presents no evidence of its own harm.

E. <u>The Public Interest Does Not Support A Stay</u>

Apple repeats the public-interest arguments the Commission and the President have repeatedly rejected in this matter and in the *AliveCor* matter (now pending before this Court). As the Commission correctly found, "the public interest does not support a stay pending appeal, and in fact ***counsels against granting a stay***." Stay-Add-14; *see also* Stay-Add-138-141 (denying Apple request to delay enforcement). The Commission found the "public interest favors the protection of intellectual

property rights by excluding infringing products." Stay-Add-14. Apple agrees when asserting patents against Masimo. MAS-ADD-449 (arguing "there is a strong public policy interest in the enforcement of patent rights").

As with its irreparable-harm arguments, Apple's public-interest arguments are unconnected to the claimed inventions. Apple argues that millions of "would-be Watch purchasers will rely on the accused products" for many reasons "***that go far beyond the inventions claimed***." Stay-Mot. 21. It points to "potentially lifesaving features—such as the Irregular Heart Rhythm Notification [(IHRN)] feature and the ECG app." *Id*. But both those features are unrelated to the claimed pulse oximetry inventions. Moreover, the Watch SE has the IHRN feature. The IHRN feature and the ECG app were also on Apple's Series 4 & 5 Watches, which did not include pulse oximetry and are also not subject to exclusion. MAS-ADD-458 (Apple Watch comparison chart).

Apple argues the remedial orders "pose an immediate setback for medical research, where the Apple Watch plays a critical role." Stay-Mot. 21. It points to studies that are underway. *Id*. But Apple says nothing about the infringing blood-oxygen sensor, instead pointing to features in watches not at issue.

Moreover, Apple ignores the Commission's finding that "[t]here are numerous reasonable substitutes for infringing Apple Watches available in the United States for both Apple Watch users who use the devices for personal, health-

related use and for users who are using infringing Apple Watches to participate in medical studies." Stay-Add-114.

Furthermore, as the Commission found, the remedial orders "cover only new imports of infringing Apple Watches" and "[t]hus, the Commission's remedy will not prevent current study participants using infringing Apple Watches from continuing to participate in research studies." Stay-Add-127. Current research study participants, like the general population, also can repair or replace their infringing Apple Watches should they fall under the remedial orders' exemptions. *Id.* Thus, the Commission correctly found "little evidence of ongoing studies that require infringing Apple Watches" and multiple suitable substitute devices for current and future medical research studies. *Id*. at 91-92, 97.

Apple also ignores the numerous third-party submissions on public interest identified in the Commission's Final Determination. Some of the nation's leading physicians explained how the Apple Watches are unreliable and even dangerous. For example:

> (1) Dr. Ward of the University of Michigan explained the Apple Watch "endangers public health" and the "parameters provided and advertised by Apple simply do not have the fidelity and accuracy required for medical decision making." MAS-ADD-345-347.

(2) The Medical Device Manufacturers Association explained Apple Watch is a mere toy. MAS-ADD-372.

(3) Dr. Goldstein, a prominent neonatologist at Loma Linda University Medical Center, explained "The incorrect perception that Apple's pulse oximetry feature includes reliable technology could lead to both false positives and false negatives, hurting the public welfare." MAS-ADD-353.

(4) Dr. Pronovost at University Hospitals explained the Apple Watch puts "patients at risk for misdiagnosis and harm." MAS-ADD-358.

(5) The Patient Safety Movement Foundation explained it believes the Apple Watch is "potentially dangerous to the public, particularly given Apple's historic marketing of the feature." MAS-ADD-364.

See also Kiani ¶¶ 77-81.

The Commission acknowledged "[o]ther researchers, medical professionals, and commenters… [went] so far as [to] ***discourage*** reliance on Apple's blood oxygen saturation feature." Stay-Add-119 (citing numerous third-party statements). Unfortunately, Apple promotes the watch as lifesaving, even though such claims are unrelated to pulse oximetry.

Apple's arguments regarding impact to the economy also do not support a stay. The Commission correctly found Apple does not specify how many jobs are particularly related to the infringing Apple Watches, as opposed to all the other non-

infringing products and services offered by Apple. Stay-Add-143. Apple cannot demonstrate any of the Commission's findings lack substantial evidence.

III. CONCLUSION

Apple has not shown any of the *Standard Havens* factors favor a stay pending appeal. All four factors weigh against a stay. Accordingly, this Court should deny Apple's motion to stay.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 10, 2024

By: /s/ *Joseph R. Re*
Joseph R. Re

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.

CERTIFICATE OF INTEREST

Counsel for Intervenors Masimo Corporation and Cercacor Laboratories, Inc. certifies the following:

1. The full name of the parties represented by me is:

Masimo Corporation
52 Discovery
Irvine, CA 92618
Telephone: 949-297-7000

Cercacor Laboratories, Inc.
15750 Alton Pkwy
Irvine, CA 92618
Telephone: 800-610-8522

2. The name of the real party in interest represented by me is:

N/A

3. Full name of all parent corporations and all publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Masimo Corporation has no parent corporation. BlackRock, Inc. owns at least 10% of Masimo Corporation's stock.

Cercacor Laboratories, Inc. has no parent corporation and no publicly held company owns at least 10% of Cercacor Laboratories, Inc's stock.

4. Other than those who have already made an appearance in this Appeal, the name of all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this Court are:

Knobbe, Martens, Olson & Bear, LLP: Ted M. Cannon, Irfan A. Lateef, Alan G. Laquer, Kendall M. Loebbaka, Carol Pitzel Cruz, Douglas B. Wentzel, Daniel C. Kiang, William R. Zimmerman, Karl W. Kowallis, and Matthew S. Friedrichs.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are as follows:

Apple Inc. v. Masimo Corporation et al., 1:22-cv-01378-MN (D. Del).

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 10, 2024

By: /s/ *Joseph R. Re*
Joseph R. Re

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.

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July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Date: 01/10/2024

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Name: Joseph R. Re

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2). This brief contains 5,186 words, including a manual count of 15 words from the figures and excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

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KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 10, 2024

By: /s/ *Joseph R. Re*
Joseph R. Re

Counsel for Intervenors
Masimo Corporation and
Cercacor Laboratories, Inc.